INTERCEPT PHARMACEUTICALS INC
Form 8-K
April 04, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 8-K

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CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **April 4, 2018**

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Intercept Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

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Delaware	**001-35668**	**22-3868459**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10 Hudson Yards, 37th Floor

New York, NY 10001

(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(646) 747-1000**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
¨Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
¨Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
¨Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 8.01. Other Events.

Intercept Pharmaceuticals, Inc. (the "Company") has previously indicated that it expects the quarter ended March 31, 2018 to be a transitional quarter for the Company. In February 2018, the Company announced that the Ocaliva label in the United States was updated by the U.S. Food and Drug Administration (the "FDA") to include a boxed warning and a dosing table that reinforce the existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis. The FDA issued an updated drug safety communication to accompany the revised label. As a result of the label update, the Company embarked on a significant outreach program to educate physicians, payers and thought leaders.

For the quarter ended March 31, 2018, the Company expects total Ocaliva prescriptions filled to be substantially consistent with total Ocaliva prescriptions filled during the quarter ended December 31, 2017. In addition, as the Company has previously indicated, based primarily on the impact in the first quarter of 2018 of increased gross-to-net deductions relating to the annual resetting of deductibles and the Medicare Part D coverage gap, the Company currently expects total gross-to-net deductions in the first quarter of 2018 to be towards the higher end of its previously announced 10% to 15% gross-to-net range. As a result, while the Company's belief in the long-term growth opportunity for primary biliary cholangitis ("PBC") in the remainder of 2018 and beyond remains unchanged, the Company expects that net sales of Ocaliva for the quarter ended March 31, 2018 will be slightly lower than net sales of Ocaliva for the quarter ended December 31, 2017.

The above information reflects the Company's preliminary results based on currently available information. The Company's internal closing procedures with respect to the periods presented above are not complete. As a result, the Company's final results may vary from the preliminary results presented above. The Company's actual results for the three months ended March 31, 2018 have not been finalized and may differ materially from the above estimates. Accordingly, you should not place undue reliance upon these preliminary results.

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the timing and potential commercial success of Ocaliva in PBC and the Company's strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by the Company's management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks. Actual results may differ materially from historical results or those anticipated or predicted by the Company's forward-looking statements as a

result of various important factors, including, but not limited to, the impact of general economic, industry, market or political conditions and the other risks and uncertainties identified in the Company's periodic filings, including the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTERCEPT
PHARMACEUTICALS, INC.

By: /s/ Sandip Kapadia
Name: Sandip Kapadia
Title: Chief Financial Officer

Date: April 4, 2018